

## REMARKS

The remarks and arguments in the following response are numbered to correspond to the numbers used in the office action.

1. The typographical error in claim 1 wherein the word "carrier" was written as "carier" has been corrected.

The claims 4 – 9 have been renumbered because the numeral "4" for claim 4 was inadvertently repeated for the following claim which should have been numbered as "claim 5", and the error was not noticed when the original claims were submitted.

The renumbered claims 5 – 10 are listed as being "(currently amended)" because of the renumbering of the last six claims.

3. The rejection of claims 1 – 9, currently renumbered as 1 – 10, under 35 U.S.C. §103(a) as being unpatentable over the teachings of U.S. Patent No. 6,036,945 to Deblasi et al is respectfully traversed.

4. The office action states that Deblasi et al disclose a delivery system for at least one sunscreen active comprising a solvent and a wax, which is heated to 150°C then cooled rapidly while stirring (claim 27). The solvent can be jojoba oil or linseed oil (claim 30). The recrystallization of the wax takes place between 25 and 50°C and the particle size of the wax particles is between one to eight microns (column 3, lines 42-60). The concentration of the wax is 10-40% by weight and the solvent concentration is 20-89% by weight (column 7, lines 30-34).

The foregoing is consistent with the disclosure of the '945 patent which focuses the invention as follows:

"The present invention provides a lubricating wax product, containing particles of very small size, which may either be *a fine micronized powder derived from a recrystallized melt blend*, or a *paste derived from a recrystallized dispersion when a solvent is used*." (see col 4, lines 26 – 31, italics provided).

More specifically, referring to claim 27 of the '945 patent, Deblasi et al state that the delivery system is obtained from the method comprising the steps of: "selecting *at least one liquid solvent* in which said at least one sunscreen active is not readily soluble alone (*sic*); selecting at least *one solid organic wax lubricant* that is *capable of functioning as a cosolvent* to enable said at least one sunscreen active to be dissolved readily in said at least one solvent at a temperature within a range of from about 70°C to about 50°C.;" (see claim 27, lines 59 – 67).

If no sunscreen active is to be used, why would one skilled in the art look to using any of the other components of the '945 composition?

Further, the only solid organic wax lubricant which can be chosen if one first establishes that it can function as a cosolvent.

The office action states:

"While the reference does not cite the viscosity of the composition, since the ingredients and the concentrations are similar, the rheology is expected to be similar too."

The '945 reference clearly states that the finely divided particles are formed by recrystallization and that the resulting product is a powder mixture characterized as being a pasty wax alloy dispersion consisting of mixed crystals of the organic wax lubricant and active ingredient. The rheology is given by the reference.

The office action further states:

"As far as the rise in temperature during the mixture is concerned, that is inherent in the process. It would have been obvious to one having ordinary skill in the art, at the time the invention was made, to select jojoba oil or linseed oil from a list of equivalents."

The point is that the rise in temperature is specified is because it is a measure of the minimum amount of energy required further to diminish the size of any of the larger among the already very small particles. The particles derive their ultrafine

particle size because of being physically subdivided by the forces to which the colloidal solution is subjected. They are never recrystallized.

The term “recrystallization” is defined as follows:

recrystallization (Chem)      The process of reforming crystals, usually by dissolving them, concentrating the solution, and thus permitting the crystals to reform. Frequently performed in the process of purification of a substance.

and,

recrystallization (Eng)      Stage in the annealing process of cold-worked metals above about  $0.4 - 0.5 T_m$ , in which deformed crystals are replaced by a new generation of crystals, which begin to grow at certain points in the deformed metal and eventually absorb the deformed crystals. The new crystals have more equal axes and contain far fewer dislocations than the deformed ones. See **annealing**. Cf **grain growth, recovery**.

(*Chamber's Dictionary of Science and Technology*, Chamber Harrap Publishers Ltd. 1999)

Note that right at the outset, in the Abstract, Deblasi et al state:

“The *recrystallization process* of the present invention produces small particle size alloys from molten mixtures and recrystallized small particle size dispersions *from high temperature solvent solutions*.” (second sentence of Abstract)

In contrast, right at the outset, in the Abstract, applicant states:

“A waxy solid having ultrafine particles homogeneously distributed in a *mixture* of vegetable oil and waxy solid, the oil being present in a major proportion by weight, forms a homogeneous *colloidal solution* which is then *cooled and subjected to high shear* to form ultrafine particles of the waxy solid, in situ, in a size range from about  $0.1 \mu\text{m}$  to  $10 \mu\text{m}$ . The resulting stiff gel . . .” (italics provided)

Applicant never forms a solution from which “small particle alloys” are recrystallized because applicant never forms a solution in the first place.

Applicant has used the term “colloidal solution” (above and in the entire specification) to specify ultrafine particles not readily separable by filtration, which

particles are distributed in a *mixture of vegetable oil and waxy solid*, not a solution. The reason the term “colloidal solution” is used is because the very fine particles of waxy solid are suspended in a *liquid phase*, as opposed to very fine particles of waxy solid suspended as a dispersion in the *gel phase*, so as to emphasize and distinguish between the liquid and gel phases.

The very fine particles of waxy solid must first be suspended in the liquid phase, so that it is “essential that the waxy solid be present in the *dispersed phase of the gel* in ultrafine particulate form.” (see specification pg 5, lines 5 – 6), so as to form the carrier gel which is stated to be “a colloid in which the dispersed phase of waxy solid particles has combined with the continuous phase of vegetable oil to produce a semi-solid material.” (see specification pg 2, lines 19 – 20).

The specification also states that “To ensure an average particle size smaller than 10  $\mu\text{m}$  in the gel, the waxy solid is melted in the vegetable oil to form a colloidal solution. It is critical that the colloidal solution be then cooled to a temperature below 38°C (100°F) before being further homogenized in a high-shear mixture to form the gel, and that the resulting gel be cooled while in the colloid mill or homogenizer so that the temperature does not rise above 49°C (120°F).” (see pg 5, lines 6 – 11).

Simply put, because the molten wax is in a liquid suspension of a naturally occurring vegetable oil, present in a major proportion by weight, and the wax is so finely divided, it is referred to as a colloidal solution. When that mixture is cooled enough to form a gel, the vegetable oil and wax are no longer liquid, the waxy particles constitute the dispersed phase and the dispersion medium is oil, (see specification pg 2, lines 21 – 24, and pg 5, lines 15 – 16) the physical characterization of the mixture being a gel.

The use of the term “colloidal solution” in the specification is consistent with the accepted usage and meaning of the term as set forth below:

“By a colloidal solution one understands a solution, in which the solved particles are present in such a small grain size that they cannot be separated by filtration. The solved particles are larger than molecules, but they are smaller than fillers in suspensions. Therefore these colloidal solutions behave partly like genuine solutions.

In order to keep such colloidal solutions stable and to prevent precipitations, wetting and dispersing agents as well as other additives are added. In foundries, colloidal graphite solutions are used as die coatings.” (see ©2004 *Buro fur Angewandte Mineralogie*, Dr. Stephan Rudolph b-47918 Tonisvorst)

This usage of the term “colloidal solution” is also consistent with its usage in the claims of at least a couple of hundred U.S. patents, e.g. U.S. Patent No. 3,934,051 in the disclosure of which the patentees refer to:

“Sodium caseinate is manufactured by treating a suspension of casein in water with caustic soda resulting in a homogeneous liquid colloidal solution which shows no tendency for casein solids to settle out. This liquid is then spray dried to obtain a dry powder.”

The basic ‘945 invention is stated as follows:

“The solid organic wax lubricant and the active ingredient are heated together to an elevated temperature with stirring, after which the molten alloy solution is cast as a thin sheet and thereby cooled. . . . The resulting solid is subsequently milled, for example by chopping and then micronizing to a fine particle size in a fluid energy mill or any other appropriate fine particle-producing mill, yielding a powder alloy which, when . . .” (see specification col 3, lines 21 – 32)

What is made is a powder alloy.

A particular embodiment of the ‘945 invention is stated as follows:

“. . . the solid organic wax lubricant and the active ingredient are melted and dissolved with stirring in at least one liquid solvent, in which either the solid organic wax lubricant alone or the active ingredient alone is not ordinarily soluble, even at elevated temperature. Thus, each component of the wax lubricant/active ingredient pair is considered to be the "cosolvent" of (or in the alternative, to be a wetting agent for) the other component of the pair. The mixture is heated to an elevated temperature, for example, from about 60°C to 175°C in order to effect a miscible, clear solution. When that solution is cooled rapidly from the elevated temperature range to a non-elevated temperature range, for example from about 25°C to about 50°C, recrystallization takes place, yielding a pasty wax alloy dispersion consisting of mixed

crystals of the organic wax lubricant and active ingredient, . . . .” (see specification col 3, lines 42 – 57).

What is made is a pasty wax alloy dispersion consisting of mixed crystals.

In neither case is there any suggestion to make a gel and no motivation of any sort to make one.

The office action is based on a conclusion arrived at after the desirability of making a gel was derived from a reading of applicant’s specification. The issue cannot be whether it is obvious to make applicant’s gel once its desirability has been ascertained; the issue is whether it is obvious to make the gel to solve the problem addressed by the applicant.

The office action has not accorded sufficient weight to the particular problem confronted and solved by the applicant. That problem is clearly stated in applicant’s specification, as follows:

a carrier having physical properties comparable to those of petrolatum;  
required to

(i) have a naturally occurring vegetable oil as a major component by weight and be substantially free of any pigment, solvent including water, or surfactant, and

(ii) incorporate up to 15% by weight of an inert micron-sized solid which has no cosmetic function, as does a pigment, without being destabilized at 40°C.

(see specification, pg 1, lines 12 – 19).

Deblasi et al not only did not address the same problem as the applicant, since they wanted to make a powder mixture (solid), not a gel, they went about making their solid by recrystallizing from a solution, not as applicant has done by dispersing ultrafine particles of waxy solid in a major proportion by weight of naturally occurring vegetable oil in a two stage process. The two stage process requires, first making a colloidal solution and cooling it, (see specification pg 3, lines 23 – 29); and then mixing the cool slurry with sufficient energy to generate the ultrafine particles and simultaneously cooling the slurry to a gel.

It is now evident from the foregoing, that the position of the office action, namely, that the claimed composition and method are *prima facie* obvious, is not supported by the disclosure of the Debasi et al patent.

The office action has not adhered to the basic tenets of patent law by which the obviousness of an invention is to be judged, namely:

- (1) the claimed invention must be considered as a whole (35 U.S.C. 103: see e.g. *Jones v. Hardy*, 727 F.2d 1524, 1529, 220 USPQ 1021, 1024 (Fed. Cir. 1984) (though the difference between the claimed invention and prior art may seem slight, it may also have been the key to advancement of the art);
- (2) the references must be considered as a whole and suggest the desirability and thus the obviousness of making the combination (see e.g. *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984); and,
- (3) the reference must be viewed without the benefit of hindsight vision afforded by the claimed invention (e.g. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983);" see *Hodosh v. Block Drug Co., Inc.*, 229 USPQ 182 (CAFC 1986). Footnote 5 on pg 187.

The office action has offered no reason why one having ordinary skill in the art having read the disclosure of the '945 patent and taking it as a whole, would suddenly be motivated not to make a powder mixture but a gel. Further, having decided to do so, why would one decide to make the gel without recrystallizing ultrafine particles from a solution.

In view of the foregoing remarks, arguments, and amendments to the specification and the claims, it is respectfully submitted that the basis for the rejection has been overcome and that the amended claims are now in condition for allowance.

Respectfully submitted,



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